

**REMARKS**

The Examiner is thanked for the due consideration given the application.

Upon entry of this amendment claims 3, 5-10, 12, 17 and 18 are pending in the application. By this amendment claims 1, 2, 4, 11 and 19-24 are canceled. Independent claim 3 has been amended to generally incorporate subject matter from claims 1 and 4. Other claim amendments improve language and antecedent basis.

No new matter is believed to be added to the application by this amendment.

Entry of this amendment under 37 CFR §1.116 is respectfully requested because it cancels claims, reduces issues and places the application in condition for allowance.

**Claim Objections**

Claims 1, 3, 9 and 21 have been objected to as containing informalities.

The Office Action asserts that 95% lacks an appropriate unit. However, this limitation has been better defined as 95wt%, which is clear to one of ordinary skill.

**Rejection Under 35 USC §103(a)**

Claims 1-12 and 17-24 have been rejected under 35 USC §102(e) as being anticipated by McLachlan (U.S. Publication 20020166129). This rejection is respectfully traversed.

The present invention, as instantly claimed, pertains to a method of treating hypercholesterolemia, hyperlipidemia or

atherosclerosis in a mammal. This method entails orally administering a composition of  $\beta$ -casein where the  $\beta$ -casein is at least 95 wt%  $\beta$ -casein A<sup>2</sup>. A serum level of any one or more of:

- a) cholesterol;
- b) low density lipoprotein (LDL) cholesterol relative to high density lipoprotein (HDL) cholesterol;
- c) low density lipoprotein (LDL) cholesterol;
- d) very low density lipoprotein (VLDL) cholesterol;
- e) apolipoprotein B; or
- f) triglycerides

after administration of the composition is lower than the serum level before administration of the composition. See instant claim 3.

McLachlan pertains to milk and milk products for preventing or treating heart disease. McLachlan utilizes milk which is free of  $\beta$ -casein A<sup>1</sup> protein in the prevention or treatment of coronary heart disease. In addition, a process for the testing of DNA from cells obtained from lactating bovines for the presence of DNA encoding certain  $\beta$ -casein proteins, selecting the bovines on the basis of the testing, and then milking those bovines to produce milk free of  $\beta$ -casein A<sup>1</sup> for use in the prevention or treatment of coronary heart disease is disclosed. See Abstract.

McLachlan does not teach or suggest in any way the treatment of hypercholesterolemia, hyperlipidemia or atherosclerosis. McLachlan teaches the treatment of coronary heart disease, but this is not the same thing as the treatment of hypercholesterolemia, hyperlipidemia or atherosclerosis.

However the Office Action asserts: "While McLachlan does not explicitly teach the limitations of cholesterol, LDL cholesterol, apolipoprotein B or triglycerides, these limitations would be inherently reduced upon the administration of  $\beta$ -casein A<sup>2</sup> for the treatment of coronary heart disease."

But even if one assumes arguendo that these limitations are inherent, this purported inherency is no bar to patentability.

Accidental results not intended and not appreciated do not constitute anticipation. *Eibel Processing Co. v. Minnesota and Ontario Paper Co.*, 261 US 45 (1923); *Mycogen Plant Science, Inc. v. Monsanto Co.*, 243 F.3d 1316, 1336, 5 USPQ2d 1030, 1053 (2001). Further, the Federal Circuit stated in *In re Robertson*, that "to establish inherency, extrinsic evidence must make clear that the missing descriptive matter was necessarily present in the thing described in the reference, and would be so recognized by persons with ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d

1949 (Fed. Cir. 1999). Further, it has been held that the mere fact that a certain thing may result from a given set of circumstances is not sufficient, and occasional results are not inherent. *MEHL/Biophile International v. Milgram*, 192 F.3d 1362, 52 USPQ2d 1303 (Fed. Cir. 1999).

In this case, no evidence has been provided that the limitations in question are inherently present in McLachlan's treatment of heart disease.

Also, instant independent claim 3 is more specifically directed to the "species" of hypercholesterolemia, hyperlipidemia or atherosclerosis. This appears to be more specific than the "genus" of reducing serum levels in cholesterol, LDL relative to HDL, etc.

In contrast, McLachlan teaches the broad genus of treating coronary heart disease.

Even if one can argue a link between coronary heart disease and hypercholesterolemia, hyperlipidemia or atherosclerosis, the disclosure of the "general" genus does not mean the disclosure of a "specific" species.

The issue of genus/species in the context of inherency is discussed in the Manual of Patent Examination Procedure (MPEP) Section 2112(IV), which states:

Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential

*applications of its discoveries." Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a **genus** still does not inherently disclose all **species** within that broad category" but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species. (Emphasis added).*

Further, as noted above, the burden is upon the Office in order support the conclusion of inherency: "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)* (Emphasis in original)."

As a result, McLachlan does not anticipate independent claim 3 of the present invention, which is specifically directed to the "species" of hypercholesterolemia, hyperlipidemia or arteriosclerosis. Claims depending upon claim 3 are patentable over McLachlan for at least the above reasons.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

Conclusion

Prior art cited but not utilized is believed to be non-pertinent to the instant claims.

The objections and rejection are believed to have been overcome, obviated or rendered moot and that no issues remain. The Examiner is accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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